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Is Automation An Elixir For Bringing Speed And Efficiency To Clinical Trials Development Processes?

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This article was first published in Clinical Informatics News (clinicalinformaticsnews.com) on Jan 08, 2019

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According to McKinsey & Company, automating 50% to 70% of tasks has resulted in annual run-rate cost efficiencies of 25% to 30%, process-time reductions of 50% to 60% and triple-digit returns on investment (ROI) across different industries. Could clinical trials see that sort of return on investment?

Before we dive deep into intelligence automation and its implications for clinical trials, we first need to understand the difference between "standard automation" and "intelligent automation." For that, we need to define robotic process automation or RPA.

In simple terms, RPA software imitates activities of a human as that person performs a specific task within a process. RPA completes repetitive tasks (or replaces manual clicks) more quickly and accurately than a human can, and it never tires. This software frees human employees for other tasks that require a human's emotional intelligence, reasoning abilities, judgment and interactions with customers. RPA software includes bots, which can be thought of as digital employees. Bots may be defined differently in licensing agreements, but one bot equates to 24 hours of human time spent performing multiple tasks for different individual processes. For example, if a process takes 4 hours to complete, 20 hours are remaining with the bot to complete other processes.

The benefits of implementing RPA fall primarily into four areas:

- Reducing process time
- Increasing throughput
- Enhancing accuracy
- Saving full-time equivalent (FTE) hours

A superset of RPA is intelligent process automation (IPA). It includes an evolving set of technologies that combine redesigns of fundamental processes with machine learning and RPA. IPA includes advanced technologies and modules, such as smart workflows, machine learning with advanced analytics, cognitive agents, and a natural-language processing engine.

Smart workflows monitor and track, in real time, the information exchanged between people and systems. Machine learning helps with intelligent decision-making by enabling rule-based decisions. Cognitive agents provide suggestions to customers. Natural-language generation (NLG) converts and interprets text-heavy, language-based communications.

Process inefficiencies across the clinical trial value chain

The existing clinical trial value chain is driven by manual processes. Intelligent automation has the potential to significantly impact many touchpoints across these processes, including study startup, study conduct, and study closeout, as well as regulatory submissions.

In the study planning and design phase, for example, considerable time is spent trying to locate information and in interpreting the diverse ways critical protocol elements are described or defined. This can lead to delays, errors and sometimes both. Currently, there is no standard or workflow for protocol review and design. Also, protocol authoring and the review process are specific. This makes it difficult for sponsors and other investigators to consistently find the information they need across all documents and to trust that the meaning in protocol content is the same across all trials.

During study startup, a lack of automation-based workflows between protocol authoring and electronic case-report forms (e-CRFs) means there is no link among the rules, transformation, and mappings between protocol parameters and e-CRF pages. This results in misaligned standards and metadata definitions across key therapeutic areas. It also limits the ability to utilize industry best practices and dictionaries, such as MedDRA, for reusability, visibility, and maintenance.

In the study execution phase, additional data elements are fed into electronic clinical applications, such as electronic data capture (EDC), electronic trial master file (eTMF) and randomization and trial support management (RTSM) systems, as well as clinical trial management systems (CTMS). Data from additional sources, including mobile devices, wearables, electronic health records (EHRs), and lab and image files, is collected for select observational studies. The amalgamation of such data sources often hinges on manual edit checks, which can result in inconsistent signal detection, transcription errors, and assessment and narrative mismatches. Plus, during the study closeout phase, the timing of key processes, such as database archival and validation, is spurious.

Using intelligent automation for clinical trial process improvement Intelligent automation can remove inefficiencies in manual processes thanks to its combination of RPA, intelligent workflows, natural language processing (NLP) and cognitive agents. Depending on the use case, intelligence automation modules can be created using these elements separately or in combinations.

In the study design phase, for example, you can establish auto-enabled protocol templates with fielded texts and metatags. NLP can digitize trial design elements and standard protocol libraries. Common data models and visualizations can enable cognitive agents.

During study startup, bot-based data checks and mappings with machine-readable study definition elements (from data acquisition to review and submission data sets, tables, figures and listings) can be used. Bot-based ancillary standards using a graph database can be used to create semantic relationships.

In the study execution phase, a metadata-based transaction system with scripts and alerts can manage workflows across data collection (study visits and consent forms/e-source connectors), data management (change control workflows and synchronization across protocols) and data submissions (study data tabulation model [SDTM], analysis data model [ADaM] mappings and algorithms). Bot-driven cascade and machine-readable instructions can be used for study closeout procedures, such as automatic database archival, bot-based data validation and cleanup, and analysis and reporting through standard mappings and algorithms. Closed-loop data and process management workflows have audit and inspection readiness capabilities.

Additionally, pharmacovigilance (PV) processes require a lot of time and resources. In an average year, a large pharma company can process anywhere from 300,000 to 700,000 adverse event (AE) cases. With mounting pressure to be leaner and more efficient, companies need to be able to automate the case load while reducing current expenses. As therapeutic areas become more complex, companies are also looking to automation to reduce errors in signal detection and more accurately report AE cases. Thus, deploying an intelligent automation-driven PV application is necessary. In this approach, bots drive the entire process—from case receipt to reporting. By automating the process end-to-end, pharma stakeholders can use human capital for more productive and proactive safety surveillance activities.

Utilizing intelligent automation for PV processes, such as signal detection and characterization through adjudication, results in several key differentiating advantages:

- Data privacy, security, scalability and performance
- Scheduled quarterly updates and end-to-end integrated validation
- Highly automated and smart workflows
- Easy interface with software-as-a-service (SaaS) application and data sources, such as labs, electronic medical records, and EHRs
- Intelligent data on products, events and case processing data
- Zero-touch case processing based on artificial intelligence (AI) and NLP
- Multitenant cloud-based approach

Using a multitenant cloud driven by intelligent automation provides pharmaceutical companies a complete 360-degree view of data and information management, from signal detection through labelling.

Any intelligent automation implementation across the clinical trial value chain must be governed and managed based on a standard operating model. Before employing an intelligent automation program across the pharmaceutical research and development (R&D) landscape, key considerations need to be clarified.

Pharmaceutical companies should draw a detailed roadmap for the implementation. This will help identify all enhancement opportunities for clinical R&D processes. A roadmap will also prioritize IPA initiatives by business unit, so each group can balance the impact of its investments against the feasibility and cost of scaling solutions, based on the initial use case.

It's important to build a strong proof of concept based on the use cases identified, for example: trial design, protocol authoring, or PV process automation. Early proofs of concept for clinical processes can enable quick wins that will secure support from the clinical R&D study team, safety groups, investigators, and executive sponsors. This support can help companies develop programs to reach the potential of a full IPA transformation initiative.

Furthermore, clinical trial processes need to be prioritized on a case-by-case basis and define a priority roadmap for the level of intelligent automation that each process requires, with clearly justified ROI.

Creating a clinical center of automation excellence can help companies sustain and grow any intelligent automation initiative. This center drives the systematic capture of value. Periodic design-thinking workshops can enhance capabilities, and training sessions can help the workforce accept the adoption of cognitive agents and bots for specific processes across the clinical study design, startup, build and execution phases.

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